UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 26, 2006

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

MEMORANDUM

SUBJECT: Assessment Guidance for Perchlorate

FROM: Susan Parker Bodine
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TO: Regional Administrators

This guidance replaces previous Office of Solid Waste and Emergency Response (OSWER) guidance and the accompanying questions and answers (referenced below) regarding perchlorate under the National Oil and Hazardous Substances Contingency Plan (National Contingency Plan, NCP), 40 CFR Part 300. As explained below, following the National Academy of Sciences' National Research Council (NRC) review, EPA adopted a reference dose (RfD) for perchlorate of 0.0007 milligram/kilogram-day (mg/kg-day), and this guidance applies that to EPA's CERCLA program. This RfD leads to a Drinking Water Equivalent Level (DWEL) of 24.5 micrograms/liter (ug/L) or 24.5 parts per billion (ppb).

Previous guidance on this topic included the 2003 guidance entitled "Status of EPA's Interim Assessment Guidance for Perchlorate," and the accompanying questions and answers, as well as the 1999 "Interim Assessment Guidance for Perchlorate." Those past guidances endorsed use of the provisional RfD range, 0.0001 to 0.0005 mg/kg-day, until the final health risk benchmark was established. They went on to use the standard default body weight (70 kg, approximately 154 pounds) and water consumption level (2 liters/day [L/day]) to calculate a DWEL of 4-18 ppb that was used as a recommended screening level.

Several agencies, including EPA, asked the NRC to review perchlorate toxicity. NRC's January 2005 final report, "Health Implications of Perchlorate Ingestion," recommended an RfD of 0.0007 mg/kg-day. Based on the NRC report and their recommended RfD, the EPA Integrated Risk Information System (IRIS) perchlorate RfD is now 0.0007 mg/kg-day. This IRIS RfD is now a value "to be considered" (TBC) in accordance with section 300.400(g)(3) of the NCP. As suggested by the NCP's preamble (55 Fed. Reg. 8745 (1990)), and subsequent guidance (OSWER Directive 9285.7-53 (2003)), use of the RfD in EPA's IRIS is preferred and consistent with the NCP's intent. EPA has determined that the RfD recommended by NRC and adopted by EPA represents the best available science regarding the toxicity of perchlorate.

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Consequently, this IRIS RfD of 0.0007 mg/kg-day is now the appropriate value for use by risk assessors and project managers.

This RfD leads to a DWEL of 24.5 ppb. EPA calculates the DWEL using the RfD, multiplied by an adult body weight of 70 kg, and divided by a conservative tap water consumption value of 2 L/day.

The National Contingency Plan (40 CFR 300.430(e)(2)(i)(A)(1)) provides that when establishing acceptable exposure levels for use as remediation goals, consideration must be given to concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effects over a lifetime or part of a lifetime, incorporating an adequate margin of safety. The RfD for perchlorate, on which the acceptable exposure level would be based, is a conservative public health-protective value derived using an uncertainty factor to ensure protection of the most sensitive population. Specifically, because the RfD includes a full ten-fold intraspecies uncertainty factor to protect the most sensitive population, the fetuses of pregnant women who might have hypothyroidism or iodide deficiency, it is also protective of other sensitive populations such as neonates and developing children. As noted in the IRIS summary for perchlorate, an uncertainty factor of ten was viewed by the NRC as conservative and health-protective, particularly because the RfD is based on a non-adverse effect that would precede any adverse effect resulting from perchlorate exposure. (For a more detailed discussion of EPA's basis for adopting NRC's recommended RfD for perchlorate, see EPA's IRIS summary for perchlorate at http://www.epa.gov/iris/subst/1007.htm.). In addition, the Agency's practice of using the RfD to calculate a DWEL for perchlorate using a 70 kg body weight and a water consumption value of 2 L/day is further supported in this instance by the fact that the standard weight and consumption values also represent weight and consumption values relevant for protecting the most sensitive population.

The NCP calls for development of preliminary remediation goals based on readily available information. 40 CFR 300.430(e)(2)(i). Typically, preliminary remediation goals are specific statements of desired endpoint concentrations or risk levels (55 Fed. Reg. 8713 (March 8, 1990)) that are conservative, default endpoint concentrations used in screening and initial development of remedial alternatives before consideration of information from the site-specific risk assessment. Frequently, the determining values are those requirements that are applicable or relevant and appropriate (ARAR) requirements under federal environmental or state environmental or facility siting laws, although ARARs may be waived. Where (as with perchlorate) no federal or state ARARs have been promulgated, preliminary remediation goals may as appropriate be developed based on "to be considered" (TBC) values (40 CFR 300.400(g)(3)). The RfD and its corresponding DWEL of 24.5 ppb are respectively the recommended TBC value and preliminary remediation goal for perchlorate.

The NCP provides that "preliminary remediation goals should be modified, as necessary, as more information becomes available during the RI/FS" (remedial investigation / feasibility study). (40 CFR 300.430(e)(2)(i)). RIs at sites with perchlorate contamination should be conducted with the same approach as RIs at all other sites, assessing factors such as physical characteristics of the site; characteristics or classifications of air, surface water, and groundwater; general characteristics of the waste; the extent to which the source can be adequately identified

and characterized; actual and potential exposure pathways through environmental media; actual and potential exposure routes; and other factors, as set out in 40 CFR 300.430(d). For example, the RI may indicate that individuals at a site may be exposed to perchlorate through multiple pathways. In such cases, contribution from non-water sources should be considered based on site-specific data until further national guidance on relative source contribution is developed. The Regions should consult applicable guidance, such as "Risk Assessment Guidance for Superfund: Volume I, Part A" (EPA/540/1-89/002, Dec. 1989) at pp. 8-15; and "Risk Assessment Guidance for Superfund: Volume I, Part B" (EPA/540/R-92/003, Pub. 9285.7-01B, Dec. 1991) at p. 20. If you have questions on the application of this guidance contact the Science Policy Branch of OSWER's Office of Superfund Remediation and Technology Innovation.

Final remediation goals and remedy decisions are made in accordance with 40 CFR 300.430(e) and (f) and associated provisions.